

### **REMARKS**

Claims 1-11 and 15-24 are pending in the case, no claim being amended hereby. All of the pending claims stand rejected over either Luther U.S. Patent No. 4,964,854 ("Luther") or the combination of Jagger et al U.S. Patent No. 4,781,692 and Chang et al U.S. Patent No. 5,419,766 ("Jagger" and "Chang", respectively). In that regard, claims 1-7, 9 and 15-23 stand rejected as anticipated over Luther, with remaining, dependent claims 8, 10, 11 and 24 being rejected for obviousness over Luther, and all of the claims stand rejected for obviousness over the combination of Jagger in view of Chang. As set out below, it is submitted that these rejections are in error and should be withdrawn.<sup>1</sup>

#### **Luther U.S. Patent No. 4,964,854**

Claims 1-7, 9 and 15-23 are rejected as allegedly anticipated by Luther, with the remaining claims, dependent claims 8, 10, 11, and 24 being rejected as allegedly obvious thereover. As will be explained below, Luther entirely lacks one of the claimed elements and so can neither anticipate nor render obvious the claimed invention. In particular, all of the pending claims specify a gasket defining an opening through which the needle shaft is movable. Despite the assertion in the Official Action that Luther has a gasket, it does not.

The term "gasket" is well understood to define a seal, sufficient to provide a blood-wiping action about the needle shaft as the needle tip is pulled into the tip protector. Thus, as explained in the specification, the gasket has an opening almost identical in circumference to the needle shaft, and thus allows the needle to pass through the opening, but otherwise forms a seal at the opening. Specification at page 5, lines 18-22. To provide such a seal, the inner

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<sup>1</sup> In order to streamline prosecution, the present Response focuses on certain distinctions which are submitted to be sufficient to overcome the rejections. Applicant does not waive any other argument available for patentability of any of the claims over the cited references or any other art, and reserves the right to present such arguments should that prove necessary.

surface about the opening must be effectively continuous, and so cannot have exposed gaps therealong as the gaps could serve as fluid leakage paths about the needle shaft circumference.

By contrast, the Official Action cites to spring ferrule 60 of Luther as if it were a gasket. There is simply no logical or factual basis to take such a position. As can be readily seen in Luther, the spring ferrule 60 has an open back end that in no way could be considered to be a gasket. Rather, it is simply an annular ring 62 that is much larger than the needle shaft and so does not even come close to the shaft. At the other end, it is the distal end of spring leaflets 64 of ferrule 60 which contact the needle shaft.

The leaflets are spring metal segments that define slits 66 (so-numbered in Fig. 6) extending distally from annular ring 62 all the way to the distal end of the leaflets 64, especially when a needle shaft extends therebetween. As a consequence, the "opening" defined by the leaflets does not have an effectively continuous inner surface, but instead has significant gaps defined by the slits. There are thus two exposed areas whereat fluid could readily pass along the needle shaft such that the leaflets cannot define a seal at the opening. As a factual matter, ferrule 60 is thus not a gasket as that term is readily understood (and as described in the specification).<sup>2</sup>

Under the circumstances, there is no support for the rejections based on Luther and they should be withdrawn. Nonetheless, should Examiner maintain the view that the ferrule 60 of Luther, or any other aspect of Luther, provides a gasket as that term is used in the present claims, Examiner is specifically asked to contact undersigned counsel to discuss whether amendments to the claim language would serve to obviate the rejections based on Luther.

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<sup>2</sup> In an Opposition against the European counterpart to the present application, EP 1 114 652 B1, the Opposer also argued that the spring ferrule 60 of Luther defined a gasket. Claim 1 as granted there corresponds to claim 1 as pending in this case. The Opposition Division at the EPO rightfully concluded that the term "gasket" implies an inherent sealing feature which was absent in the art relied upon by the Opposer, including Luther. That conclusion is entirely correct and supports Applicant's position here that Luther fails to anticipate the claimed invention. Should Examiner wish to see copies of any of the official paperwork from that Opposition, please contact undersigned counsel who will undertake promptly to provide same.

**Jagger et al U.S. Patent No. 4,781,692**  
**and Chang et al U.S. Patent No. 5,419,766**

All of the claims are also rejected as allegedly obvious over Jagger in view of Chang. In that regard, while Examiner now agrees that Jagger does not have the claimed blocking means of independent claim 1 or the member of independent claim 15, the Official Action takes the position that it would have been obvious to modify Jagger to have the tab of Chang. Applicant questions how that could be so.

As claimed, the blocking means or member is coupled to the tip protector in order to enclose the needle tip within the tip protector (claim 1) or with the needle tip proximal of the distal opening of the tip protector (claim 15). Yet, in Jagger, the stylet 100 is never pulled all the way into element 106 (which Examiner calls the tip protector). Instead, as readily seen in Fig. 5, the stylet is only pulled partially into that "protector" and has its sharp tip protruding beyond the distal opening of element 106 and into the flexible plastic tubular catheter 104. Were one to modify Jagger to include the tab of Chang, where would it go and what purpose would that serve?

Of course, per the present claim language, the tab would have to be coupled to element 106. If that is done, however, there is no purpose served by the tab as the stylet never pulls into element 106. Hence, the tab cannot meet the language of the claims as it could neither "enclose the distal point of the needle cannula with the tip protector" as set out in claim 1, nor be "moveable into the path between the distal point and the distal opening [of the tip protector] with the needle shaft in the second position [i.e., with the distal point proximal of the tip protector distal opening] so as to block the distal opening" as set out in claim 15. Thus, even were there any basis to add the tab to the structure of Jagger, the result would do no more than add an unnecessary component to Jagger that has no function or useful purpose. It can hardly be said to

be obvious to make such a meaningless modification. Hence, it is respectfully submitted that the rejections based on Jagger and Chang are in error and should be withdrawn.

### **Conclusion**

In view of the foregoing amendments and comments, it is respectfully submitted that the application is in condition for allowance. Accordingly, a formal Notice of Allowance is respectfully solicited. In the event that any issues remain outstanding, Examiner is invited to contact the undersigned to expedite prosecution of this application. No fee is believed due with this paper. If any fee is due or is not otherwise properly paid, the Commissioner is authorized to charge any such fee or credit any overpayment to Deposit Account No. 23-3000.

Respectfully submitted,  
WOOD, HERRON & EVANS, L.L.P.

By: /kurt l grossman/  
Kurt L. Grossman  
Reg. No. 29,799

411 Vine Street  
2700 Carew Tower  
Cincinnati, OH 45202  
(513) 241-2324  
(513) 241-6234 (fax)